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Phase II trial of gemcitabine (2,2'-difluorodeoxycytidine) in patients with adenocarcinoma of the pancreas.

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Gemcitabine is a novel nucleoside analog which demonstrated a broad spectrum of preclinical activity in solid tumor models, and responses in patients with pancreas cancer during phase I evaluation. Patients with measurable adenocarcinoma of the pancreas who had received no previous chemotherapy were eligible for this multicenter phase II clinical trial. Gemcitabine 800 mg/m2 was administered intravenously weekly for 3 consecutive weeks, followed by one week rest, every 4 weeks. Forty-four patients entered the trial; 35 had at least 2 cycles of therapy. Partial response was observed in 5 patients (11%, estimated 95% confidence interval 2-20%), with a median duration of 13 months. All responding patients had stabilization or improvement in performance status. Fourteen patients had stable disease of 4 or more months. The median WBC nadir was 3.8 x 10(3)/microliters (range 1.6-9.3) and the median absolute neutrophil (ANC) nadir was 2.0 x 10(3)/microliters (range 0.4-7.2). Thrombocytopenia - 100.0 x 10(3)/microliters was observed in 15 patients; the median platelet nadir was 123.0 (range 30.0-245.0). All patients experienced a mild to moderate flu-like syndrome. In addition, one patient had a mild hemolytic-uremic syndrome which appeared related to gemcitabine therapy. Gemicitabine demonstrated marginal activity in this resistant neoplasm, without excessive toxicity. Further evaluation, including the use of more intense dosing and/or combination therapy, is warranted.

Publication Types:

- Clinical trial
- Clinical trial, phase ii
- Multicenter study

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